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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-02-20

January 3, 2002

George G. Khouri, MD, PA
1411 N. Flagler Drive, Suite 4100
West Palm Beach, Florida 33401

Dear Dr. Khouri:

During an inspection of your firm located in West Palm Beach, Florida on August 30, 2001, FDA Investigator Michelle S. Dunaway collected information that revealed serious regulatory problems involving MicroStim Model 100 TENS units. The inspection revealed that you promote, distribute and sell Model 100 TENS units, manufactured by MicroStim Technology, Tamarac, Florida, for therapeutic treatment of age related macular degeneration (AMD). AMD is a new intended use for these device(s) for which neither premarket approval or premarket clearance has been obtained.

Under section 201(h) of the Federal Food, Drug, and Cosmetic Act, these products are devices because they are used in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body. During the inspection, the investigator documented violations of the Act resulting in the devices being adulterated within the meaning of section 501(f)(1)(B) and misbranded within the meaning of section 502(o) of the Act.

Sections 501(f)(1)(B) and 502(o)

FDA has not approved or cleared the MicroStim Model100 for the therapeutic treatment of age related macular degeneration (AMD). Promotion, distribution and sale of the MicroStim Model100 for the treatment of AMD causes it to be adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act.

The Model 100 TENS unit is adulterated under the Act because FDA has not approved a premarket approval application establishing that the device is safe and effective for this new intended use [501(f)(1)(B)].

The device is misbranded under the Act because no premarket notification has been submitted for this new intended use of the MicroStim Model 100 [502(o)].


This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the Food and Drug Administration without further notice. The actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including: (1) each step that has or will be taken to correct the current violations; (2) the timeframe within which the corrections will be completed; and (3) for any corrections that cannot be completed within 15 working days, please state the reason for the delay and the time frame within which corrections will be completed.

Please respond to Timothy J. Couzins, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

Sincerely,


for Emma R. Singleton
Director, Florida District

cc: MicroStim Technology, Inc.
7881 N.W. 90th Avenue
Tamarac, Florida 33321